DyAnsys

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of Safe Medical Devices Act (SMDA) 1990 and 21 CFR 807.92.

510(k) Number: K091397

JUL - 8 2009

Applicant Information:

Date Prepared: 1st March 2009

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Device Information:

Classification: Class II
Trade Name: ECScope 200
Common Name: ECG Monitor
Classification Name: Electrocardiograph, CFR 870.2340
Product Code: 74 DPS

Predicate Devices:

a. K Number: K070614
Model Name: CorScreen
Manufacturer:Viasys

b. K Number: K002074
Model Name: AB Cardiette Daedalus View Hes
Manufacturer: H & C Medical Devices spa

c. K Number: K080036
Model Name: Portable ECScope 12*i*
Manufacturer: DyAnsys, Inc

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Device Description:

ECScope 200 is designed to acquire, display and record ECG signals from surface electrodes. The device consists of two basic components: the processing unit and the patient acquisition module.

ECScope 200 is a multi channel electrocardiograph for the simultaneous acquisition of the 12 ECG leads i.e L1, L2, L3, aVR, aVL, aVF, V1, V2, V3, V4, V5 & V6, featuring alphanumeric display and keyboard. This product has an option to print ECG data through inbuilt 2 inch thermal printer or through external USB printer. The ECG data can also be transferred in image format to USB Key or to the computer through USB Cable.

ECScope 200 can record and store in its database up to 30 ECGs. Each ECG record includes patient data, doctor's information and ECG measurements. Stored ECG can be printed directly on inbuilt Thermal Printer or through external USB printer.

ECScope 200 has optional ECG interpretative software which gives statements and measurements that represents partial qualitative and quantitative information of the patient's general cardiovascular conditions.

Interpretation program Hanover ECG System (HES) providing the following additional information:

- Representatives templates of each lead including markers on fiducial points
- Summary of mean measurements
- Summary of measurements performed on each lead
- Rhythm Analysis Statements
- Rhythm Graphical Statements
- Signal noise detection and information
- Specific findings on QRS complex
- Conduction statements
- QRS T Diagnostic statements
- Summary of measurement performed on each lead

Intended Use:

ECScope 200 portable, battery operated 12 channel electrocardiograph is intended to be used for the diagnosis of cardiovascular system complications. ECScope 200 will acquire and record 12 ECG leads simultaneously.

ECScope 200 is intended to be used by a licensed health care practitioner or under the direct supervision of a licensed health care practitioner in a hospital or health care environment. The optional ECG interpretative statements and measurements represent partial qualitative and quantitative information of the general patient cardiovascular conditions.

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These are not intended for any specific clinical diagnosis and No therapy or drugs can be administered based solely on the interpretation statements.

The clinical significance of ECG tracings, interpretative statements and measurements must be determined by the physician in conjunction with clinician's knowledge of patient, the results of other physical examination and clinical findings.

Summary of Safety and Effectiveness

Comparison to Predicate Device(s)

The ECScope 200 is substantially equivalent to the following predicate devices:

a. K Number: K070614
Model Name: CorScreen
Manufacturer -Viasys

b. K Number: K002074
Model Name: AB Cardiette Daedalus View Hes
Manufacturer – H & C Medical Devices spa

c. K Number: K080036,
Model Name: Portable ECScope 12*i*
Manufacturer – DyAnsys, Inc

1. ECScope 200 battery operated Multi channel electrocardiograph is intended to be used for the evaluation of the cardiovascular system. ECScope 200 will acquire and record Multi channel ECG signal. ECScope 200 can store in its database up to 30 ECG signal records. The device features a 10 lead ECG.

2. The ECScope 200 has the same intended use as the legally marketed predicate devices. The intended use of the ECScope 200 is the same as the predicates.

Summary of Device Testing

The ECScope 200 was subjected to safety and performance tests against regulatory standards. Final testing for the product included various performance tests as per ANSI/AAMI EC11: 1991 Guidance Document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2009

DyAnsys, Inc.
c/o Underwriters Laboratories Inc.
333 Pfingsten Road
Northbrook, IL 60062
Attn: Ned Devine

Re: K091397
Trade/Device Name: ECScope 200
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 19, 2009
Received: June 23, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091397

Indications for Use

510(k) Number (if known): K091397

Device Name: ___ECScope 200____

Indications for Use:

ECScope 200 portable, battery operated 12 channel electrocardiographs is intended to be used for the diagnosis of cardiovascular system complications. ECScope 200 will acquire and record 12 ECG leads simultaneously.

The interpretation software is intended to support the physician in evaluating the ECG in terms of morphology and rhythm.

Interpretation results must be overviewed and approved by trained physicians. Interpretation just represents partial qualitative and quantitative information of the general patient cardiovascular conditions. No therapy or drugs can be administered based solely on the interpretation statements.

The clinical significance of the ECG tracings must be determined by the physician in conjunction with clinician's knowledge of patient, the results of physical examination and other clinical findings.

The equipments are intended to be used by trained medical personnel or physicians.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 (Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091397